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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/603,952      | 06/25/2003  | Peter Lyon Harris    | 297912001602        | 3111             |

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| EXAMINER |
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WILLSE, DAVID H

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| ART UNIT | PAPER NUMBER |
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3738

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 04/16/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/603,952

Applicant(s)

HARRIS ET AL.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 14-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on June 25, 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second end formation and second end chamber as set forth in claim 7, 8, and others must be shown or the features canceled from the claims. No new matter should be entered. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 4, line 2, "said tube" lacks a proper antecedent basis.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-11, 14, 16, 18, 19, and 21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rayhanabad, US 4,712,551, which discloses a generally tubular portion **12** and an end formation **32**. The tubular portion **12** tapers from the distal end **16** to the inlet tip **20** (column 5, lines 33-36). Because the mouth **22** defines an opening of elliptical cross section (column 5, lines 25-32) and because of the physical structure of the aorta, the end formation **32** defines a non-circular open-end perimeter. Regarding claim 2 and others, various axes are evident from the geometry of the “tube”, and the components inserted into the aorta **18** possess several concave and convex surfaces. Regarding claim 3, the difference in internal diameters between the mouth **22** and the aorta **18** inherently creates non-laminar movement of blood. Regarding claim 7 and others: attention is directed to the embodiment of Figure 8, for example. Regarding claim 18 and others, the first diameter portion is view as comprising the intermediate

section 17; as for claim 21, the first diameter portion additionally comprises the branch 51 and the distal and intermediate portions of the tubular portion 12'.

Claims 6, 15, 17, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rayhanabad, US 4,712,551. PTFE materials were well known in the art at the time of the present invention and would have been obvious from their advantageous physical properties and hemocompatibility, with Rayhanabad being open to various suitable materials (column 9, lines 5-9). Regarding claim 6, the length or “first diameter” of the enlarged chamber 34 being greater than approximately 14 mm would have been obvious from Figure 4 and the fact that an inner or “second diameter” of chamber 34 is slightly greater than about 0.33 inches (column 5, lines 29-31) in order to distribute the sealing forces over a greater area of the blood vessel.

Claims 23 and 24 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Butters et al., US 6,019,788. Figure 3, for example, illustrates a vascular prosthesis comprising a continuous ePTFE structure (column 8, lines 1-4) including a tubular part 16 and an enlarged chamber 28 and/or 22 with an oval open distal end (column 10, line 6 et seq.). Regarding claim 24, a reduced diameter of the tubular part 16 within the cuff 28 would have been inherent from the sealing attachment of the cuff onto the tubular part (column 7, line 1 et seq.) and/or from the fact that the blood conduit 16 can be stepped (column 7, lines 43-44).

#### **Response to the Applicant's Remarks**

Regarding the objection to the drawings, the Applicant references 35 U.S.C. § 113 and 37 C.F.R. § 1.81(a) and submits that “an additional drawing showing a tube 52 with a first enlargement 54 and a second enlargement 54 is not necessary for the understanding of the subject matter recited in claims 7-8” (Applicant's reply of January 29, 2007: page 7, lines 16-18).

It is clearly stated in 37 C.F.R. § 1.83(a) that the drawing “must show *every* feature of the invention *specified in the claims*” (emphasis added). The current drawings do not even show the second end, let alone the claimed features of the second end formation. Instant claim 8 is directed to a vascular prosthesis having *two* ends of generally *similar* geometries; such a prosthesis is not conveyed to the ordinary practitioner by the drawings. The Applicant has not presented any M.P.E.P. citation for supporting and quantifying the Applicant’s apparent reasoning that illustration of some features is “necessary” but not so for other features. The Applicant’s arguments thus fail to overcome the plain *requirement* that every claimed element be shown.

Regarding the Rayhanabad patent, the Applicant mischaracterizes the previous Office action (of August 31, 2006) as equating the mouth **22** with the “non-circular open end perimeter” (present claim 1, line 5). Rather, the end formation **32**, which forms part of the open end (Figure 4; column 2, lines 35-44; column 4, lines 63-66; etc.), defines a non-circular open-end perimeter (page 5, lines 1-2, of said Office action). The term “perimeter” is defined as “[t]he outer limits of an area” (*Webster’s II New Riverside University Dictionary*: 1984), and the perimeter of the end formation **32** clearly outlines a larger cross-sectional area than that of a first diameter of the tapering tubular portion **12**.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762 and who is generally available Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**